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Remarks

Bearing in mind the remarks below, the application has been amended to place it in condition for allowance. An early indication of the same would be greatly appreciated.

Support for Amended Claims 1 and 31

Claims 1 and 31 filed herewith have each been amended to refer to the fact that the orthosis is configured to resist plantarflexion and assist dorsiflexion of a foot of a patient who is experiencing abnormal plantarflexion of the foot.

Support for these amendments may be found in lines 26 to 27 of page 8 of the description.

Relevance of the Amendments to Claims 1 and 31

The amendment to these Claims has been made to clearly state that the device of the invention relieves a recognised and seriously debilitating medical condition, namely foot plantarflexion, and additionally assists dorsiflexion.

As will be explained below, Applicant believes that Davidson, which discloses a simple athletic support, has no relevance at all to a device which is configured to resist plantarflexion and assist dorsiflexion of a foot of a patient who is experiencing abnormal plantarflexion of the foot.

In the Drawings

The Examiner has indicated that Figs. 1a, 1b, 2a and 2b should be designated as "Prior Art". A letter to the Chief Draftsperson is enclosed proposing that this amendment is made to the drawings. Therefore, Applicant respectfully submits the objection should be withdrawn.

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Rejection of Application under 35 U.S.C. 103Claims 1-13, 15-20, 28-31, 33, and 34

Claims 1-13, 15-20, 28-31, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson ('343) in view of Gray ('799). Claims 3, 29, and 33 and 4-10, 16, and 28 were rejected as being unpatentable over Davidson in view of Gray and in further view of an additional cited reference. Withdrawal of the rejection is hereby respectfully requested.

The Office Action dated 18 July 2003 presents the argument that a skilled person would be motivated to combine the structure taught by Davidson with the material of the device taught by Gray to arrive at Applicant's invention.

Specifically, the argument presented requires the skilled person to adopt all of the structural features of Davidson, and then combine those features with a single feature selected from the devices disclosed in Gray.

Applicant respectfully submits that the argument presented in the Office Action is fundamentally flawed as it requires that the skilled person must start with the disclosure of Davidson, and then apply the teaching of Gray to the device disclosed in Davidson.

Davidson and Gray describe devices which have entirely different technical purposes, and which are therefore appropriate as a means for alleviating entirely different medical conditions.

Lines 1 to 12 of Column 1 of Davidson explicitly state that the device described therein:

"...is securable about the ankle and foot of the user...(and)... has a shock-absorbing structure to absorb and relieve shock imposed on the foot (sic) particularly in the heel area and which incorporates an elastic anklet."

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Lines 6 to 10 of Column 2 of Davidson state that:

"... many athletes have special problems. Gymnasts engaged in vaulting, tumbling and other gymnastic routines, often land on their feet and particularly on their heels with substantial shock."

From these two paragraphs alone it is immediately apparent that a skilled person reading Davidson would understand that the user of the device described therein is intended to be an athlete, or at the very least someone who is capable of engaging in strenuous activity.

Applicant's invention and the device disclosed in Figs. 25 and 26 of Gray, in stark contrast, are orthotic devices for use by persons who have difficulty walking - such persons, of course, being wholly incapable of "vaulting, tumbling and other gymnastic routines".

A person skilled in the art (such as a medical practitioner or medical technician) presented with a patient who suffers from foot plantarflexion would understand that a device for athletes, as described in Davidson, would be of no use to their patient as it is wholly unsuitable for use as an orthotic device for the alleviation of a foot plantarflexion condition.

It follows, therefore, that an obviousness objection that starts with the disclosure of Davidson and adds to it one feature selected from Gray cannot be correct for at least the reason that there is no motivation to combine the references.

It would, however, be entirely reasonable for the skilled person to consider recommending a device such as that disclosed in Figs. 25 and 26 of Gray for alleviating a foot plantarflexion problem, as this particular device is intended and specially designed for the alleviation of foot plantarflexion.

It is the case, therefore, that an obviousness objection that starts with the device disclosed in Gray may be a viable proposition.

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However, Applicant notes that there is absolutely no disclosure in Gray which suggests that the particular construction described therein may be modified. As such, there is no motivation in the disclosure of Gray which would point a skilled practitioner or technician to look to another document, let alone another document that pertains to a device which is wholly unsuitable for alleviating the particular medical condition for which the device of Figs. 25 and 26 of Gray would be used.

Even if the skilled practitioner or technician were to look to another document, which Applicant does not admit, they would still not be motivated by the disclosure of the documents to abandon all of the structure taught in Gray and replace that structure with an entirely different structure of a device that is wholly unsuitable for alleviating foot plantarflexion (the particular medical condition for which the device of Figs. 25 and 26 of Gray would be used).

Davidson, as explained above, is directed to reducing the shock imparted to the heel of an athlete by providing cushioning below the heel.

Applicant would respectfully submit that the only general teaching which a skilled practitioner or technician would derive from Davidson is that the heel could be cushioned to lessen the risk of damage to the heel in the course of athletic activity.

It follows, therefore, that in the highly unlikely event that a skilled practitioner were to combine Gray and Davidson, the only suggestion provided for modification of the Gray device would be to add cushioning to protect the heel of the patient - as taught in Davidson.

A device constructed in accordance with Gray and including heel padding as taught in Davidson would, of course, be very different to the device claimed by Applicant, and as such Applicant's invention cannot reasonably be said to be obvious thereover.

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The Examiner may be tempted to suggest that the reference in Davidson to an "elastic anklet" may provide the necessary motivation to the person skilled in the art to arrive at the device claimed by Applicant. Applicant would respectfully disagree.

The skilled person would immediately understand that the elastic anklet of Davidson exists merely as a means to hold the cushioning in place under the foot of the athlete, and as such is no more than a means to attach the cushioning to the patient.

The skilled person considering the hypothetical combination of Gray and Davidson might opt to replace the bands disclosed in Gray (as a means for holding the device to the foot of the Patient) with a piece of elastic (for example fastened between the two sides of the orthosis disclosed in Figs. 25 and 26), but there is no suggestion in Gray or Davidson that the elastic anklet could be entirely replaced by a silicone structure.

As such, it follows that the objection previously raised is unsustainable and should now be withdrawn.

In the event that Applicant's arguments, being as they are both logical and entirely consistent with the teachings of Gray and Davidson, are still deemed not to be persuasive, Applicant would again wish to respectfully remind the Examiner that M.P.E.P. § 2143 clearly states that to establish a *prima facie* case of obviousness, four basic criteria must be met - none of which have in fact been met by the argument expounded in the Office Action.

Applicant would also wish to draw attention to the fact that these established principles of patent law (as set out in the MPEP) have recently been reaffirmed in *Velander v. Garner* No. 02-1366, 2003 U.S. App. LEXIS 22717, at *7-*8 (Fed.

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Cir. 2003)¹ wherein Circuit Judges SCHALL, GAJARSA, and PROST stated in their written decision that:

The ultimate determination of whether an invention would have been obvious under section 103(a) is a legal conclusion based on underlying findings of fact. In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000). The underlying factual inquiries include (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; and (3) the differences between the claimed invention and the prior art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). If all the elements of an invention are found in a combination of prior art references, a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991) (citing In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988)). Both the suggestion and the reasonable expectation of success "must be founded in the prior art, not in the Applicant's disclosure." Id.

The key points to note from this Court of Appeal decision are that: "a proper analysis of § 103 requires" (our emphasis), inter alia, the following factor to be considered:

"(1) whether the prior art would have suggested to those of ordinary skill in the art that they SHOULD make the claimed composition or device, or carry out the claimed process;..."

¹ a recent US Court of Appeals for the Federal Circuit Decision decided on 5 November 2003 (an appeal from a decision issued by the USPTO Board of Patent Appeals and Interferences in respect of Interference No. 104,242)

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It is clear from the wording used that the factors set out for a proper analysis of § 103 are not optional, but a requirement.

It is also clear that it is not sufficient merely to determine whether the prior art *could* or *may* have suggested a particular combination of features disclosed therein. Rather, it is a requirement of a proper obviousness analysis to consider whether the prior art would have suggested that the skilled person should make the combination of features claimed.

Considering again the disclosure of Gray and Davidson, it cannot reasonably be said that the disclosure provided therein would suggest to someone of ordinary skill in the art that they should either: (a) abandon all the structure of Gray and replace it with the structure of Davidson, or (b) adopt the structure of Davidson, abandon all the structure of Gray and select only the material disclosed.

As the Office Action fails to show that the disclosure provided in Gray and Davidson would suggest to someone of ordinary skill in the art that they should make the device claimed by Applicant, it follows that the requirements identified by the Circuit Judges for a proper analysis under § 103 have not been met, and hence that the objection previously raised is unlawful.

In light of the foregoing and the clarifying amendments submitted, Applicant would respectfully submit that the obviousness objection previously raised should now be withdrawn.

Independent Claim 31

Independent claim 31 was rejected as being unpatentable over Davidson in view of Gray. This rejection is respectfully traversed.

First, as described above, there is no motivation to combine the Davidson and Gray references. Therefore, claim 31

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is novel and non-obvious over the cited references for at least this reason.

Furthermore, the cited references, either singly or in combination, fail to teach or suggest a first region having a first resilience and a second region having a second resilience, where the second resilience is greater than a first resilience and the second region overlies at least a portion of the dorsal aspect. In rejecting this claim the Examiner states, "[i]t is inherent that the second region of the tubular portion may have a resilience greater than the first region of the tubular portion..." Office action, at 3. Applicant strongly disagrees.

Davidson was concerned with providing a shock absorbing heel cup in an anklet. With regard to the anklet, Davison states, "[t]he materials of fabrication of the anklet may vary but the main characteristic of the material is that the material should have elastic properties so that the material will stretch..." Davidson, col. 3, lines 46-49. Davidson fails to make a distinction between the material of the anklet as a whole and the material of regions of the anklet including a dorsal aspect, as Davidson was only concerned with the anklet material as a whole. Therefore, it is not inherent in Davidson that the second region of the tubular portion, including the dorsal aspect, has a resiliency greater than the first region.

Further, Gray, which was also cited against claim 31, fails to supplement the missing teachings of Davidson. Specifically, with regard to materials utilized in the splint of Gray, Gray states, "[p]referably the splint body 12 is integrally molded of an elastomeric material, such as silicone rubber." Gray, col. 5, lines 55-57. Thus, Gray was not concerned with materials of particular regions, including a dorsal region, of the splint, especially as compared to other regions. Therefore, it is not inherent in Gray that the second region of the tubular portion, including the dorsal aspect, has a resiliency greater than the first region.

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The Examiner merely states that resiliency of the structure are inherent without providing support. Patentee respectfully points out that the Examiner must refrain from using the teachings of the specification in determining obviousness. The Federal Circuit articulated this well established rule as follows:

It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. *Orthopedic equipment Co. v. U.S.* 702 F. 2d 1005, 1112 (Fed. Cir. 1983).

In contrast to Davidson and Gray, Applicant's claim 31 makes a distinction between the L-shaped structure as a whole and regions of the L-shaped structure including a second region which overlies at least a portion of the dorsal aspect. Specifically, claim 31 recites, "the structure having an outer surface consisting of a first region having a first resilience and a second region with a second resilience that is greater than said first resilience; wherein said structure is configured so that said second region overlies at least a portion of a dorsal aspect of the patient's foot and a portion of the patient's lower leg when the orthosis is worn by the patient..." The invention is advantageous for at least the reason that it that resists plantarflexion and assists in dorsiflexion in patients. Applicant's specification, page 8, lines 26-27.

These elements are not taught or suggested in the cited references. Therefore, for at least this reason, claim 31 is novel and non-obvious over the cited references. Accordingly, withdrawal of the rejection to claim 31 is respectfully requested.

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Dependent Claims 3, 29, and 33

Claims 3, 29, and 33 were rejected as being unpatentable over Davidson and Gray, and further in view of Mance. This rejection is respectfully traversed.

First, as described above, there is no motivation to combine Davidson and Gray. Therefore, the claims are non-obvious over the cited references for at least this reason.

Further, with reference to dependent claim 3, the Examiner states, "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a reinforcing means comprising a length of tape joined together in a figure-eight position...in place of the reinforcing means disclosed by Davidson, since Davidson discloses that the reinforcing means may be positioned and tightened as the user desires to provide additional support (col. 6, lines 1-7)..." Office action, at 4 and 5. Applicant respectfully disagrees.

Davidson discloses two straps, namely straps 200 and straps 202. With regard to these straps, Davidson states they are "stitched or otherwise secured to the anklet at one end 205." Davidson, col. 5, line 68 to col. 6, lines 1-2. "The distal ends of the straps extend at least partially about the foot and ankle and are securable at mating fastener sections 210 on the strap and 212 at a predetermined location on the anklet." Davidson, col. 6, line 2-5. "The user may position and tighten the straps to provide additional support as desired." Davidson, col. 6, line 5-7. Applicant respectfully submits that Davidson merely discloses that the straps may be tightly positioned about the foot or ankle. Davidson, col. 6, lines 5-7. Davidson fails to teach or suggest that a figure-of-eight form, or any other reinforcing means for that matter, should be substituted for its disclosed straps. Therefore, there is no motivation to combine Davidson with Mance, and for at least this reason, the cited references fail to teach or suggest the claimed invention. Accordingly, the rejection to claim 3 should be withdrawn.

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In making the rejection to claim 29, the Examiner indicates that straps 200 and 202 of Davidson are the reinforcing means of Davidson. Applicant respectfully submits that the reinforcing means of Davidson are not contiguous. Therefore, Davidson fails to teach or suggest elements of claim 29, for at least this reason.

Additionally, Mance fails to supplement the missing teachings for at least the reason that there is no motivation to combine the Davidson and Mance references, as stated above with regard to claim 3. Further, claim 29 recites, "[a]n orthosis according to Claim 2, wherein said reinforcing means comprises a first region of said peripheral wall of said first tubular structure and a second region of a peripheral wall of said second tubular structure, wherein said first and second regions are contiguous and a resilience of said first and second tubular portion peripheral walls inside said first and second regions is greater than a resilience of said first and second tubular portion peripheral walls outside of said first and second regions." The foot support of Mance does not teach or suggest whether the straps are of a greater or lesser resilience than the other portions of the foot support of Mance, and for at least this additional reason, Mance fails to teach or suggest elements of the claimed invention. Therefore, the rejection to claim 29 should be withdrawn.

With regard to claim 33, the Examiner recites, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made... to incorporate the tubular portion enveloping the patient's toes, as taught by Mance, into the device disclosed by Davidson, as an alternative means of protecting the toes of the user against abutting surfaces." Office action, at 4-5. Applicant strongly disagrees.

Davidson teaches away from such a combination as it discloses, "[t]he device leaves a substantial portion of the user's foot free so the device may be used by gymnasts and other athletes where a high degree of tactile sensitivity is required." Davidson, col. 2, lines 47-50. Additionally,

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Davidson recites, "[t]he configuration of the device leaves a forward portion of the user's foot unimpeded for good tactile feel and toe and ball boot gripping as required in many athletic activities." Davidson, col. 4, lines 65-68. Therefore, there would be no motivation to modify Davidson such that the toes are enveloped, as Davidson teaches away from such a modification.

For at least this reason, claim 33, which recites, "said tubular portion additionally envelopes both the patient's toes and the patient's calcaneum" is novel and non-obvious over the cited prior art for at least the reasons provided above. Accordingly, the rejection to the claim should be withdrawn.

Dependent Claims 4, 10, 16, and 28

Claims 4, 10, 16, and 28 were rejected as being unpatentable over Davidson and Gray, and further in view of Boudon. This rejection is respectfully traversed.

First, Applicant respectfully submits that there is no motivation to combine Davidson and Gray, as described above. Therefore, the claims are non-obvious over the cited references for at least this reason.

Further, with reference to dependent claim 4, the Examiner states that neither Gray nor Davidson discloses the reinforcing means comprising a rib but that Boudon supplements the missing teaching. Specifically, the Examiner states, "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a reinforcing means comprising a rib, as taught by Boudon, into the device disclosed by Davidson as an alternative reinforcing means...." Office action, at 5. Applicant strongly disagrees. As stated above with regard to claim 3, the Examiner refers to the pair of straps of Davidson as the reinforcing means. Davidson discloses that the straps' position may be altered to tighten the straps. Davidson does not teach or suggest that a rib, or any other reinforcing means for that matter, should be

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substituted for the straps. Thus, for at least this reason, the cited references fail to teach or suggest elements of claim 4. Accordingly, the rejection to claim 4 should be withdrawn for at least this reason.

With regard to claim 10, the Examiner asserts, "[i]t is inherent that the rib may have a greater resilience than the resilience of the first and second tubular portions, since the rib may be molded from a variety of materials." Office action, at 5. Applicant strongly disagrees. None of the cited references teach or suggest that the rib may have a greater resilience than the resilience of the first and second tubular portions. With regard to Boudon, first and second tubular portions are not taught or suggested, therefore, Boudon could not contemplate the resiliency of the tubular portions with respect to the rib. With regard to Davidson, the rib is not taught or suggested, thus Davidson could not contemplate the resiliency of the tubular portions with respect to the rib. Accordingly, the Examiner cannot argue the inherency of the claimed element of resiliency, as it is not disclosed in either of the references. Patentee respectfully points out that the Examiner must refrain from using the teachings of the specification in determining obviousness.

Thus, Applicant submits that claim 10 is novel and non-obvious over the cited references for at least these reasons. Further, claim 10 depends from claim 4 and is novel and non-obvious over the cited references for the at least the same reasons provided above with regard to claim 4. Accordingly, the rejection to claim 10 should be withdrawn.

In making the rejection to claim 16, the Examiner states, "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made... to incorporate a second portion not enveloping the patient's calcaneum, as taught by Boudon, into the device disclosed by Davidson, since the separation of parts involves only routine skill in the art and forming the anklet disclosed by Davidson

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without the heel cup portion would, therefore, only involve routine skill in the art." Office action, at 5-6. This rejection is respectfully traversed.

The Examiner argues that separation of parts involves only routine skill in the art, thus it would be obvious to incorporate a second portion not enveloping the patient's calcaneum (heel), as taught by Boudon, into the device disclosed by Davidson. However, Applicant strongly disagrees with this reasoning as a principle of operation of Davidson was to provide a heel cup designed to fit over the heel area of the wearer. Applicant respectfully submits that Davidson was concerned with providing "a novel and unique foot cushioning device which includes a heel cup designed to fit over the heel area of the wearer." Davidson, col. 2, lines 24-26. The M.P.E.P. explicitly states that if "the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." M.P.E.P. § 2143.01, 2100-127 (February 2003) (citing *In re Ratti*, 123 USPQ 349 (CCPA 1959)). Therefore, Applicant, respectfully submits that it is impermissible for the Examiner to propose modification of Davidson such that it does not include the heel cup, as this would change a principle of operation of the prior art invention being modified.

In contrast to Davidson, whose invention was concerned with providing a shock absorbing heel member, Applicant's claim 16 recites, "[a]n orthosis according to Claim 1, wherein said second tubular portion does not envelope the patient's calcaneum." Accordingly, for at least the reasons presented above, claim 16 is novel and non-obvious over the cited references. Thus, withdrawal of the rejection to the claim is respectfully requested.

With regard to claim 28, the Examiner asserts, "[i]t is inherent that the rib may be formed integrally with the first and second tubular portions (Fig. 3), since forming

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parts integrally involves only routine skill in the art." Office action, at 5. This rejection is respectfully traversed.

As stated above, with regard to claim 4, Davidson does not teach or suggest that a rib, or any other reinforcing means for that matter, should be substituted for the straps of Davidson. Therefore, for at least the reason that Davidson fails to contemplate a rib, Davidson could not possibly contemplate a rib formed integrally with first and second portions, as recited in claim 28. Furthermore, assuming for the sake of argument that there were motivation to combine Davidson with Boudon, there is no teaching or suggestion that the foot support of Boudon should be integrally formed with first and second tubular portions. Boudon fails to teach or suggest first and second tubular portions, and for at least this reason, could not teach or suggest that the rib is integrally formed with first and second tubular portions.

In contrast, Applicant's claim 28 recites, "said rib is integrally formed with said first and second tubular portions." Thus, for at least these reasons, the cited references fail to teach or suggest the claimed invention. Accordingly, the rejection to claim 28 should be withdrawn.

Summary

The Argument expounded in the Office Action requires the skilled person to select a device which is wholly inappropriate for treating the condition that is the subject of Applicant's invention, and then modify that device.

Skilled persons such as medical practitioners and technicians do not advise patients to use devices which are not suitable for alleviating the ailments of those patients. To do otherwise would, we submit, be at the least unprofessional and at worst grossly negligent.

It is clear therefore that an argument which requires the selection of an inappropriate device is fanciful, and wrong.

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In addition, it is noted that the M.P.E.P. and established principles of Patent Law require, for an obviousness objection, for the prior art to suggest "to those of ordinary skill in the art that they should make the claimed...device".

Davidson does not suggest that the device disclosed therein could be used for alleviating plantarflexion, and hence the suggestion that a skilled reader would consider Davidson is not "founded in the prior art", but has instead been arrived at following consideration of Applicant's invention.

Even if one skilled in the art were to combine Gray and Davidson, they would not arrive at the invention claimed. At best all they would provide is the structure disclosed in Figs. 25 and 26 of Gray with under-heel cushioning (as disclosed in Davidson), and a strip of elastic by means of which the structure may be secured to the patient.

The skilled person would not be motivated to abandon the structure of a suitable device, adopt the structure of a wholly unsuitable device, and adapt that unsuitable device to arrive at Applicant's invention.

Further, additional arguments presented above with regard to independent claim 31 and dependent claims 3, 4, 10, 16, 28, 29, and 33 indicate that the cited references fail to render the claimed invention anticipated or obvious.

In light of the foregoing, Applicant would respectfully submit that the objection raised is wholly unsustainable and should now be withdrawn.

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Conclusion

In view of the above comments it is respectfully submitted that amended claims 1 and 31 are allowable over Gray or Davidson considered alone or in isolation.

The remaining claims are allowable, if only by virtue of their dependence from an allowable main claim. Further, additional arguments presented above with regard to dependent claims 3, 4, 10, 16, 28, 29, and 33 indicate that the cited references fail to render the claimed invention anticipated or obvious.

It is therefore believed that all of the pending claims of this application are in condition for allowance, and early notice to that effect would be appreciated.

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313

Signed: *Sally Azevedo*
Typed Name: Sally Azevedo
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Respectfully submitted,

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